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09/698,213	10/30/2000	James D. McInnch	04983.0220.00US00/38-10(1	6072

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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

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18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/698,213	MCININCH, JAMES D.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *17-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendments and remarks in Paper No. 17, filed 10/30/02, are acknowledged.

Applicant requests that a Supplemental Information Disclosure Statement (submitted November 9, 2000) listing one reference be initialed, signed, dated, and sent back to the Applicant. Unfortunately, the Examiner is unable to locate the above-referenced 1449 form and requests the Applicant to resend another copy of the 1449 form as well as the reference if he desires it to be considered in the examination.

Applicant's arguments, filed 10/30/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-16 and 41-44 are herein under examination.

Claims Rejections – 35 U.S.C. 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention. The support for the amended claim 15 as pointed to by the applicant

(throughout the specification, specifically on page 17, lines 17-20) does not support the new claim limitation of a window which "is about 75 to about 100 nucleotides." Written basis is provided for a window of 100 nucleotides as stated on page 17, line 20, but not for the range approximately 75 to 125 nucleotides. Because the introduction of "about 75 to about 125 nucleotides" lacks written basis for amended claim 15, as filed in Paper No. 17 on 10/30/02, it is considered NEW MATTER.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 1-16 and 41-44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-16 and 41-44 are rejected because the specification, while being enabling for the following:

Initial oligonucleotide probability	p. 21, equation I,
Transition probability	p. 22, equation II,
Nucleic acid sequence probability	p. 23, equation III, and
Probability for each nucleotide state	p. 24, equation IV,

the specification does not reasonably provide enablement for any method of computation for determining the above probabilities. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant application fails to provide guidance to one of ordinary skill in the art for generating the probability values of the following by any other means than by the four equations indicated above. The specification does not provide or suggest what any other substitutable methods of computation could be for the above probability determinations thus not enabling one of ordinary skill in the art to know what calculations to perform. While the specification provides some guidance for a method of determining a probability value for the above listing using the particular equations or values disclosed, the specification does not provide guidance for a method of determining the probability by any other means. The specification does not provide working examples of the methods described using any other means of computing the described probability values. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and

the unpredictability of generating probability values, the specification as filed is not enabling for any method of determining the listed probability values as claimed. The instant application is only enabled for the above-mentioned computational means of the four probabilities.

This rejection is reiterated from the previous Office Action and maintained for reasons of record.

Applicant argues that other probability models and algorithms are taught such as on page 19, lines 22-27, and page 22, lines 16-17. Consideration of page 19, lines 22-27, and page 22, lines 16-17, reveals that probabilities should be calculated via prior art references. In order to broaden the scope of the instant invention the disclosures of such printed publications are essential material. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 11 contain a mathematical equation which is confusing as it incorporates "Φ (f)" representing bias which cancels itself out in each equation, and therefore nullifies its effect on the equation.

Claim 1 recites the phrase "said probability of said nucleic acid sequence" which is vague and indefinite due to the lack of clear antecedent basis for the noted phrase in part d) of claim 1. The only probability that is previously set forth in the claim is in part c) wherein apparently several probabilities are determined. That is, part c) determines a probability for said nucleic acid sequence for each of said states. This apparently is a plurality of probabilities, one for each state. Therefore, which probability is utilized in part d) of claim 1 which requires usage of apparently a singular "probability of said nucleic acid sequence"? This lack of antecedent basis and unclear wording is also present in other independent claims 7, 8 (regarding part d) said window probability), 41, 42 (part a) probability of a window), 43, and 44(part d) said window probability). This rejection is also applicable to claims 2-6 and 9-16 which are claims dependent from said independent claims due to their direct or indirect dependence.

The following rejections under 35 U.S.C. 112, second paragraph, are reiterated from the previous Office Action and maintained for reasons of record.

Claims 1, 7, 8 and 41-44 are vague and indefinite due to the lack of clarity in the phrase "based upon" (i.e. claim 1, line 8). It is unclear as to what are the metes and bounds of the

parameters that determine how much basis is included upon the determinations. Claims 2-6 and 9-16 are also indefinite due to their dependency from claims 1 and 8.

Applicant disagrees with the rejection under 35 U.S.C. 112, second paragraph, because the detailed computational methods given the specification. This is not found persuasive because the applicant still has not defined exactly what bases and to what degree they should be drawn upon to determine the probability of the instant invention. As set forth in the previous action, a clarification of the metes and bounds is required to improve the clarity of these claims.

The term "capable" in claim 7 is a relative term that renders the claim indefinite. The term "capable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant alleges that "capable" is not indefinite because the skilled artisan could readily ascertain whether the "determining" step is capable of accepting a bias. This is not found persuasive because the determination of a probability requires a statistical model and any such model consists of equations which are inherently capable of accepting a bias, in various forms such as multiplicative or additive.

Claims 3 and 11 are vague and indefinite due to the lack of clarity in the following terms: $\boldsymbol{f}$, $\mathbf{S}$, $\mathbf{P_f}$, $\mathbf{P_i}$, and $\mathbf{\Phi}$. It is unclear as to what are the metes and bounds of these terms.

Applicant disagrees with the indefiniteness of $\boldsymbol{f}$, $\mathbf{S}$, $\mathbf{P_f}$, $\mathbf{P_i}$, and $\mathbf{\Phi}$, because they are clearly defined in the specification. As set forth in the previous action, a clarification of the metes and bounds is required, by listing in the claim the exact definition of each term.

Claims 8 and 44 lack clarity in step c) due to the claim language "determining a probability for said window for each of said states." Claims 9-16 are also indefinite due to their dependency from claim 8.

Applicant correctly noted that the phrase mentioned in the previous action ("for said window for said nucleotide") was not present in either of claims 8 or 44. However, the phrase in the previous paragraph is contained in these claims which is confusing as a probability cannot be determined for a window, but rather the states found in the window. Careful consideration of the syntax, particularly the arrangement of prepositional phrases within the claims, will improve the coherence of the claims as well as the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7-9, 12, 13, 15, and 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Borodovsky et al. (*Computers Chem.*, 1993).

This rejection is reiterated from the previous Office Action and maintained for reasons of record.

Applicant states that each and every element of a claim must appear in a single art reference and further cites claims 1, 8, and 41-44 as including the step based on a bias and claim 7 as including the phrase "capable of accepting a bias." Due to the confusion (see 35 U.S.C. 112, 2nd paragraph rejection above) of "Φ (f)" effectively canceling itself out in the equations of

claims 3 and 11, these equations are equivalent to the equations listed on page 129 (Borodovsky et al.). Being equivalent equations, if one probability (as provided by the Applicant) is "capable of accepting a bias" (claim 7, line 10), then the same probability stated by Borodovsky et al. (page 129) must also be capable of accepting a bias. Therefore, Borodovsky et al. anticipate the instant invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 2, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER